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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,443

12/20/2006

Hitoshi Kotani

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,443	Applicant(s) KOTANI ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69 and 73-94 is/are pending in the application.
- 4a) Of the above claim(s) 73-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69 and 92-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2009 has been entered. Claims 69, 73-92, and new claims 93 and 94 are pending. Claims 69 and 92-94 are under examination. Claims 73-91 are withdrawn from consideration, being drawn to non-elected subject matter.

Response to Amendment

2. The following rejections are withdrawn:
- The rejection of claim 92 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn in view of Applicant's amendment. However, note that upon further consideration of the specification, there is support for enhancement of anti-tumor immunity with HVJ-E as an adjuvant (see page 9, lines 19-20, and claims presented in the preliminary amendment of 9/26/06).
 - The rejection of claims 69 and 92 under 35 U.S.C. 102(b) as being anticipated by Kaneda (EP 1170363 A1, filed in IDS of 12/20/06) is withdrawn. Applicant's arguments were not persuasive to withdraw the rejection. The rejection is withdrawn upon further consideration of the claimed subject matter which does not appear to be enabled.

Claims Summary and Interpretation

3. Claims 1 and 92 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists essentially of* a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E), wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited. Chapter 2111.03 of the MPEP [R-3] provides guidance on the use of transitional phrase “consisting essentially of” as it defines the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. Thus Applicant’s composition does not contain any other component that interferes with the ability of HVJ-E to inhibit tumor cell growth.

Claims 93 and 94 are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that *consists of* a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E) and a pharmaceutically acceptable carrier, wherein IL-12 and IL-16 in dendritic cells are induced or regulatory T cells are inhibited.

Claim Objections

4. Claims 92 and 94 are objected to for a typographical error. IL-16 should be IL-6.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69 and 92-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method for inhibiting tumor cell growth *in vivo* by administering a composition consisting essentially of HVJ-E, or consisting of HVJ-E and a carrier. The specification discloses that the inhibition of tumor cell growth is due to a chemotherapeutic compound that is encapsulated in the HVJ-E vector, thus implying that the vector itself is not responsible for the anti-tumor cell growth (pages 6 in its entirety, and pages 6-7, bridging paragraph, and pages 50-51, bridging paragraph). While the vector has adjuvant properties for enhancing an anti-tumor immune response (see page 8, lines 7-8, and pages 8-9, bridging paragraph), those adjuvant properties alone are not expected by one of skill in the art to have any anti-tumor cell growth without the accompanying chemotherapeutic agent.

Therefore, in view of the breadth of the claims and the teachings in the specification that clearly indicate that the chemotherapeutic agent is responsible for anti-tumor cell growth, it would require undue experimentation to practice the claimed method of inhibiting tumor cell growth with HVJ-E vectors alone.

Note that should Applicant amend the claims to recite an enabled embodiment, the art rejection over Kaneda may be reinstated.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648